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CTH-03 (5439)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re the Application of

N.A. Williams, *et al.*

Serial No.: 09/600,060

Filed: July 10, 2000

Art Unit 1644

Examiner: N. Phuong Huynh

For: AGENT FOR TREATING ALLERGIC OR HYPERSENSITIVITY CONDITION

**Reply to a Restriction Requirement Under PCT Rule 13.1 and 37 C.F.R. § 1.143**

Commissioner of Patents
and Trademarks
Washington, DC 20231

Dear Sir:

Please consider the following remarks sent in response to a Restriction Requirement dated 5 December 2000:

REMARKS

Claims 20 to 39 are pending in this application. In the above-referenced restriction requirement, these were divided into three groups:

Group I, claims 20-30, drawn to an assay method for identifying an agent useful in the treatment of an allergic or hypersensitivity condition;

Group II, claim 31, drawn to a pharmaceutical composition comprising an agent identified in the assay method; and

Group III, claims 32-39, drawn to a method of treating a subject for allergic or hypersensitivity condition.

I hereby certify that this document is today being sent as first class mail under 37 C.F.R. § 1.8, postage paid, to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

December 29, 2000

Mary M. Krinsky

In accordance with 37 C.F.R. § 1.499, applicants elect with traverse group I, drawn to an assay method for identifying an agent useful in the treatment of an allergic or hypersensitivity condition. The requirement is traversed because applicants do not agree with the examiner's assessment that the claims "do not relate to a single general inventive concept under PCT Rule 13.1" as set out in the Office Action, page 2, second to last paragraph. All three groups exhibit a unity of invention under PCT Rule 13.2 because there is a technical relationship among the claimed inventions, as they all are related to allergic or hypersensitivity conditions and share this common feature. The Office Action asserts that all the groups "have no special technical feature", citing the International Search Report and two papers, Nashar, *et al.* (*Proc. Natl. Acad. Sci. USA 93*: 226-230, 1996) and Holmgren, *et al.* (*Am. J. Trop. Med. Hyg. 50* (5 Suppl): 42-54, 1994). This appears to be a rejection on the merits rather than support for a restriction requirement, and in any event the claims in the PCT application reviewed by the EPO examiner were cancelled upon national phase entry in the U.S. Applicants believe they have made a contribution over prior art for each of the three groups, particularly groups I and II directed to assay methods for identifying useful agents and agents identified using the method.

Thus, the claims have "a community of properties justifying their grouping which [is] not repugnant to principles of scientific classification" under U.S. restriction practice [*In re Harnish*, 631 F.2d 716, 206 U.S.P.Q. 300, 305, (C.C.P.A. 1980)], and are "so linked as to form a single general inventive concept" as set down in PCT Rules 13.2, 13.3, and 13.4. In general, in the U.S. an applicant has a "right to define what he regards as his invention as he chooses, so long as his definition is distinct" [*ibid.*]. That court and its successors have long recognized the advantages to the public interest in permitting applicants to claim all aspects of the invention so as to encourage the making of a more detailed disclosure of all aspects of their discovery.

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. § 112, all aspects of what they regard as their inventions, regardless of the number of statutory classes involved.
>
> *In re Kuehl*, 177 U.S.P.Q. 250, 256 (C.C.P.A. 1973).

A search of the group directed to assay methods should lead to the references applicable to the others and should not be an undue burden for examination purposes. Moreover, requiring applicant to pay filing fees, prosecution costs, issue fees, and maintenance fees for three patents for one invention directed to the use of rho protein inhibitors for axon regeneration *is* an undue burden for applicants, particularly as they have small entity status. For these reasons, applicants respectfully request that the requirement for restriction be withdrawn or at least modified to combine groups I and II.

If the undersigned can advance the prosecution of this application in any way whatsoever, please call at the number listed below.

Respectfully submitted,

on 29 December 2000 by

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